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10/713,544	11/14/2003	R. Steven Davidson	57778.8001.US01	7965

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EXAMINER	
EBRAHIM, NABILA G	
ART UNIT	**PAPER NUMBER**
1618	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/713,544	DAVIDSON, R. STEVEN	
	Examiner	Art Unit	
	NABILA G. EBRAHIM	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *1-12 and 19-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-18,25 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *04/30/2008 and 12/12/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The receipts of Information Disclosure Statements dated 04/30/2008, 12/12/2007, amendments to the claims and applicant arguments dated 2/25/08 are acknowledged.

Status of Claims:

Claims 1-26 are pending in the application.

Claims 13-18 are under current examination.

Claims 1-12 and 19-24 were withdrawn from consideration.

Claims 25-26 are new.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 25 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claim recites "wherein the powder matrix is without an active ingredient." The specification supports a powder matrix with one or more active agents. However, there is no support for a powder matrix without an active agent. Applicant is expected to point out precisely where in the specification the support for this recitation is found. This is a new matter rejection.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

In view of claims amendments, the rejection claim 14 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is herein withdrawn.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

In view of amending the claims, the rejection of claims 13, 15, and 17 under 35 U.S.C. 102(b) as being anticipated by Leung et al. US 20010022964 is herein withdrawn.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 13-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leung et al. US 20010022964 (Leung) in view of Ismail EP0163924 (Ismail) and further in view of Richey et al., WO 1994014331 (Richey).

Leung teaches fast dissolving orally consumable films which are used to deliver breath deodorizing agents, antimicrobial agents and salivary stimulants to the oral cavity. The films can also be used to deliver pharmaceutically active agents [0001]. It is noted that the mouth bad odor is a symptom associated with pharyngitis. Consequently it would improve a condition of pharyngitis. The film also comprises menthol (abstract) and a film-forming material such as pectin [0033] in an amount from about 0.01 to about 99 wt %, preferably about 30 to about 80 wt %. Since other ingredients are recited in instant claim 17 in an amount that is possible to be 0%, then these ingredients are not limiting the claims. Pectin is used in amounts ranging from about 45 to about 70 wt % of the film and even more preferably from about 60 to about 65 wt % of the film [0033]. Further, Leung teaches menthol which can be added from about 0.01 to about 15 wt % of the composition, preferably about 2.0 to about 10 wt % and even more preferably from about 3 to about 9 wt % of the film [0031]. The film may contain water [0034] in an amount of about 0.1 to about 8 wt % (claim 10), an amount of about 0.1 to about 15wt % of at least one flavoring agent (claim 10) which may be cherry [0052]. Leung also teaches acesulfame-K (a sweetening agent), the free acid form of saccharin [0047] in an amount of about 0.1 to about 15 wt % (claim 10). Carrageenan is taught in amounts ranging from about 0 to about 10 wt %, preferably about 0.1 to about 2 wt % of the film [0042]. Sucralose is also disclosed as a sweetener agent. Leung teaches the use of lecithin, in amounts ranging from about 0.01 to about 0.7 wt % of the film [0042]. Examples 2-4 use glycerin [0148] in an amount of 2% (table 2). Leung teaches that a preservative may be added in amounts from about 0.01 wt % to about 1 wt % of the film and that the preferred preservatives include sodium benzoate [0121].

Polysorbate 80 is also used in an amount between 0.355 to 0.4 % (table 2) and a preferred thickening agents include carboxyl methylcellulose, and the like, in amounts ranging from about 0.01 to about 5 wt % [0043].

Regarding the limitation in claims 17 and 18 regarding the pectin that may be replaced with one or more of the groups consisting of gelatin, maltodexrin, modified food starch, TiO2, and acacia gum, it is noted that Leung recognized that some of these film-formers such as gelatin, high amylose starch and acacia gum are usable as film-formers in the invention, accordingly, it would have been obvious to a person of ordinary skill in the art to replace one of these substances with the other or replace some of the amount used by another substance to advance a specific property in the film produced such as rigidity, thickness or thinning, etc.

Note that the references, disclose the combination of water, cherry flavor, carrageenan, acesulfame potassium, sucralose, lecithin, benzocaine, glycerin, sodium benzoate, polysorbate, menthol, carboxymethyl cellulose, pectin and vitamin E in amounts that overlap or differ in a small amount. It has been held that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. See In re Aller, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955). Furthermore the claims differ from the reference by reciting various concentrations of the active ingredients. However, the preparation of various pharmaceutical compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. See In re Russell, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

Leung is deficient in the sense that the film formulation disclosed does not comprise vitamin E.

Ismail teaches Vitamin E ointments, gels, creams and drops for protection of eyes against oxygen and free radicals and treatment and prophylaxis of inflammatory processes (title) wherein the agent for the treatment and for the protection of the mucous membranes of the eyes and of the nose and of the throat contains vitamin E, where appropriate combined with other vitamins and additives (abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add vitamin E to the film dosage form disclosed by Leung for treating pharyngitis because Ismail teaches that vitamin E is effective in treating and prophylaxis against inflammation of the mucous membranes. The person of ordinary skill would expect success in providing a method of improving the symptoms of pharyngitis and consequently cough.

Neither of the references teaches the powder matrix coating.

Richey teaches coated chewing gum product comprises a gum pellet coated with a coating (abstract). A method to improve coating processes using sugars or alditols is to add a powder coating after a liquid coating (page 7, lines 18+). Applicant claims a powder matrix as a coating for the film dosage form, however, the specification does not define the said “matrix".

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add a powder-coating to the film dosage form because powdery coatings are fast dissolving and would not hinder the rapid dissolution of the dosage form.

Accordingly, the powder coating disclosed by Richey reads on the claims. Further the disclosure reads on new claim 25 since Richey does not teach any active agent in the coating. Finally, new claim 26 requires that the film causes numbness for

treating cough or pharyngitis; it is obvious that the effect of the anesthetic active agent included in the composition is numbness. Note also that Leung teaches that if this effect is not desired, the composition should be coated with conventional materials that are known in the art [124]. Thus the current amendments are known in the art and do differentiate the instant claims.

Response to Arguments

Applicant's arguments with respect to claims 13-18 and 25-26 have been considered but are moot in view of the new ground(s) of rejection.

Applicant argues that the amendments to claim 13 which read "placing an edible film comprising an active ingredient and a film former into an oral cavity wherein said edible film is coated with a powder matrix." Neither Leung nor Ismail teach or suggest the limitations of the claims as amended. This renders moot in view of introducing Richey to the rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NABILA G. EBRAHIM whose telephone number is (571)272-8151. The examiner can normally be reached on 8:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nabila G Ebrahim/
Examiner, Art Unit 1618

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618